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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,177	10/29/1999	UPVAN NARANG	100448.01	6878
27049	7590	11/03/2004	EXAMINER	
OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/430,177	NARANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32,34-51 and 76-144 is/are pending in the application.
- 4a) Of the above claim(s) 4,13,14,26-32,34-49,76-110 and 122-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,15-25,50,51 and 122-144 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 08/16/04. Examiner also acknowledges receipt of supplemental declaration filed 10/20/04. Claims 1-32, 34-51 and 76-114 are pending; of these, claims 4, 13, 14, 26-32, 34-49, 76-110 and 122-144 are withdrawn from consideration.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 08/16/04 has been entered.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-3, 5-12, 15-25, 50, 51 and 111-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung (WO 96/40797) in view of Engelson et al. (U.S. 5,531,715).

Leung provides a method for applying polymerization initiators to an applicator tip, comprising dipping the applicator tip in a liquid medium, specifically a low boiling point solvent, containing the initiator and drying the applicator tip (See p. 17, line 18 to p. 18, line 15), and includes anionic surfactants, such as polysorbate 20 and polysorbate 80, poloxamers, cationic surfactants, such as tetrabutylammonium bromide, and amphoteric or zwitterionic surfactants, such as dodecyldimethyl (3-sulfopropyl) ammonium hydroxide, among the initiators used in the invention (See p. 16, lines 18-35). The alkylbenzyltrimethylammonium chloride claimed in claim

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5 of the instant application, also known as benzalkonium chloride, is a cationic surfactant. Additionally, Leung includes alpha-cyanoacrylates, which are known as anti-fungals and antibacterial agents, among the polymerizable materials used in the invention (See p. 7, line 23 to p. 8, line 33) and initiators activated by stimulation, such as heat or light, among the initiators, which may be applied to the applicator tip (See p. 17, lines 14-28). The crystal violet claimed by Applicant in claims 7-9 of the instant application is activated by light.

Thus, Leung discloses a method comprising dipping an applicator tip in a solution comprising agents as claimed by Applicant in claims 1-3 and 5-12, and drying the applicator tip. Leung teaches that the liquid medium includes non-aqueous solvents, such as ether, acetone and ethanol, and mixtures thereof (See p. 17, lines 24-28). Thus, with regard to claims 1-3, 5-12 and 15-17, Leung provides the general teachings that the liquid medium is preferably a low boiling point solvent (See p. 17, lines 27-28), however, the prior art is deficient in that it fails to specifically include methanol among the solvents used in the invention. The examiner relies on Engelson (See below) for the teachings that initiators may be dissolved in methanol. With regard to claim 18, Leung teaches that the initiator on the applicator tip may be present in a variety of concentrations in the medium and the amount depends on process conditions (See p. 17 lines 29-35). Regarding claims 19-25, 50 and 51 Leung teaches that the device of the invention comprises a container and a plunger for forcing the material from the container and an applicator tip (See p. 12, line 36 to p. 14, line 9), and the initiator may be applied to the applicator tip during the fabrication of the tip (See p. 18, lines 1-6) or the applicator tip may be detachable from the applicator container holding the polymerizable material (See p. 14, lines 10-20). Leung teaches that the applicator tip can be made of plastics, foams, rubber or film, and the material may be porous (See p. 15, lines 10-22), and the applicator tip may be dried in a vacuum

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oven (See p. 18, lines 7-15).

With respect to claims 111-121, Leung teaches that the polymerizable material used in the invention, comprising alpha-cyanoacrylate (See p. 7, line 23 to p. 8, line 33), are useful as tissue adhesives, sealants for preventing bleeding or covering open wounds, systems for delivering bioactive agents and providing implants (See p. 19, lines 19-34), the tip may be a tube, cannula or catheter, and the container may be a syringe, a tube or a vial (See p. 13, line 20 to p. 14, line 9).

Engelson discloses a method for applying a polymer coating to a catheter, comprising dipping the catheter into a solution comprising initiators dissolved in a solvent, which is preferably a low molecular weight alcohol and ether, especially methanol, ethanol and mixtures thereof (See col. 4, lines 31-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions disclosed by Leung, by dissolving the initiator in methanol. The expected result would have been a successful method of applying an agent to an applicator tip and successful applicator tips. Because of the teachings of Leung, that the liquid medium is preferably a low boiling point solvent, and the teachings of Engelson that ether, methanol, ethanol and propanol are considered equivalent in the art, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing an applicator tip with the desired agent. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

**Applicants Remarks:**

*Restriction/Election Requirement*

Applicants request reconsideration of the restriction/election requirement of 01/03/01 on the basis that the restriction requirement is improper. Examiner agrees with applicants that regarding the election requirement, upon the allowance of the elected claims, the search will be extended to non-elected species/claims. The request has been considered and upon further review of the claims, the restriction/election requirement is proper. Group I is directed to a method of applying an agent to an applicator tip and the invention in Group I is drawn to a method of making an applicator composition. The invention of group III is directed to an applicator composition. The methods of group I and II involve different steps. The composition of group III does not contain a bioactive material or flavorant that are part of the invention of group II. A quick examination of claim 4 will indicate that the active agents of this claim do not overlap the active agents of claim 3. Thus, the requirement is proper and continues to be maintained.

***Response to Arguments***

4. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Applicants argue that the cited references do not teach the claimed invention and therefore, the rejection with respect to the claims should be withdrawn. In the remarks filed June 29, 2004, applicants argue that Engelson does not teach equivalency of the solvents for all uses and that applicants have demonstrated unexpected result.

Leung clearly discloses the instant method except that Leung does not use methanol, hence an obviousness rejection. It is respectfully noted that the rejection is not anticipatory in light of the failure of Leung to use methanol. However, the secondary reference, Engelson is relied upon for a teaching that initiators are dissolved in methanol. It is prima facie obvious to take in the initiator composition of Leung and put it into methanol with the expectation that the initiator

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composition of Leung will dissolve in the methanol. The comprising language does not exclude the presence of other solvents.

**Response to supplemental declaration**

It is respectfully noted that the instant claims are directed to method of applying at least one agent selected from..., the method comprises...; wherein the low boiling solvent is methanol,... and not to setting times. The declaration, per the declarant applicant, compares the effect of different solvents for an initiator for the cyanoacrylate. The generic claim broadly claims initiator and Engelson discloses dissolving initiator in methanol and ethanol and this represents a disclosure that methanol can dissolve an initiator. The primary reference, Leung dissolves the initiator containing composition in ethanol or acetone or ether. Applicants' declaration is not commensurate with the scope of the claims because the claims do not compare the effect of different solvents on cyanoacrylate. The instant claims are not directed to the setting times of cyanoacrylate in various solvents and therefore, the declaration is not commensurate with the claims. The generic claim does not recite ppm amounts of methanol. Applicants' declare that the slight difference in the amounts of methanol and acetone and ethanol does not present varying results and applicants failed to provide the data. Secondly, there is no showing that the methanol as disclosed by Engelson would not work in the composition of Leung as it relates to application of the Leung's composition to applicator tip or catheter.

*Applicants' Request for Interview*

Examiner will follow this action with a telephone call to applicants' representative to set up the interview date and time. Applicant is by this action afforded the opportunity to review the rejection in preparation for the interview.

No claim is allowed.

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5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'mfubara', is written over the printed name 'Blessing Fubara'.